

10TH ANNUAL SYMPOSIUM

**Clinical & Pharmaceutical Solutions through Analysis** 



Translating Challenges in the Biotechnology Industry: From Drug Discovery to the Clinic



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### **WELCOME**

### **Inspiration to Application**

April 10, 2019

Dear Colleague:

On behalf of the organizing committee and our sponsors, we welcome you to the 10th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2019). It is a pleasure to host this unique event once again in Shanghai.

The goal of the CPSA Shanghai annual meetings is to provide in-depth reviews of innovative technology and industry practices through open discussion of industry related issues and needs. The diversified symposia and sponsored events are designed to be highly interactive where scientists openly share their experiences and visions in a collegial setting. The program will highlight speakers and sessions that provide firsthand experiences with new technologies as well as critical insights into industrial workflows and regulatory issues.

The theme of this year's annual meeting "Translating Challenges in the Biotechnology Industry: From Drug Discovery to the Clinic" is reflected in the pre-conference events, symposia sessions and sponsored workshops. An annual pre-conference workshop held in Chinese on Clinical Trials in China will be lead by Tianyi Zhang of Frontage. The Keynote Lecture Series, a new event in 2017, will this year feature Dafang Zhong of The Shanghai Institute of Materia Medica, who will discuss "Covalent Binding of Irreversible Targeted Anticancer Drugs to Plasma Proteins." This special event will be presented in Chinese.

Plenary Lectures will be delivered by Petr Vachal from Merck, on "The Invention of MK-8262, a CETP Inhibitor Backup to Anacetrapib (with Best in Class" and Professor Huwei Liu of Peking University, on "Ultrasensitive Ambient Mass Spectrometry Immunoassays: Detection of Protein Biomarkers of Some Cancers." CPSA traditions continue in Shanghai as the Symposia Sessions, Poster Sessions, CPSA EXPO, Innovator Award Session, and Young Scientist Session will help make our annual meeting a most unique event. We will endeavor to connect everyone, not only as friends, but also as scientists across different disciplines in drug R&D.

Imagination and stimulating discussion are central to each CPSA function and session – or as we say around the world – CPSA is user friendly! We aim to bring scientists together from both East and West; and thus, CPSA Shanghai continues to foster our unique meeting tradition that encourages diverse thinking, understanding, and relationships. Our hope is for attendees to actively participate in the conference and to become inspired with new ideas, new relations, and new collaborations.

Special thanks are extended to our sponsors who all share their sincere belief that CPSA Shanghai is indeed the premier international event to meet experts in the field and to openly discuss our industry's most fundamental challenges. Each sponsor shares the passion and commitment for the sciences – on an international scale.

Enjoy the annual meeting Where Technology and Solutions Meet ...and of course, where East meets West!

Mike S. Lee, Ph.D. CPSA Founder

Min Liu, Ph.D. 2019 Program Chair



### ORGANIZING COMMITTEE

#### **PROGRAM CHAIR**

Min Liu Merck USA

#### **ORGANIZING COMMITTEE**

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**Petr Vachal** 

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Jonathan Wang

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**New Objective** USA

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### **SPONSORS**

#### Thank You!

The CPSA Shanghai annual symposium is made possible by the broad-based support of industry sponsors. The passion for the analytical sciences and the accelerated discovery and development of pharmaceuticals is shared by each sponsor. As a result, the event is dedicated to promoting awareness and understanding of the issues and needs associated with pharmaceutical R&D in the hopes of inspiring significant advances in the field.



























**Media Sponsors** 







### **EXHIBITORS**

#### Thank You!

We would like to extend ours sincere thanks to the exhibitors who made this year's annual CPSA Shanghai conference possible. It is with the support and commitment of these companies and people that technology can meet solutions! We hope to see you all in 2020!























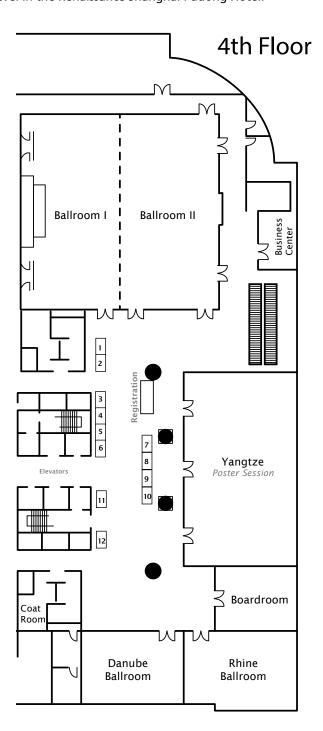






### FLOOR PLAN

The CPSA Shanghai symposia, roundtables, poster session, EXPO and workshops will be held on the 4th Floor Lobby Level in the Renaissance Shanghai Pudong Hotel.



#### **EXPO HOURS**

The CPSA Shanghai 2019 Exposition will be open on the following schedule, but many company representatives will be on hand throughout the conference.

THURSDAY 11:00 AM - 2:00 PM FRIDAY 11:00 AM - 2:00 PM

#### **EXHIBITORS**

Booth#	Company
1	Antpedia
8	Biopredic/QuanYang
6	ChemPartner
10	Covance
12	ES Industries
5	Frontage Laboratories
3	Instrument.com.cn
11	Medicilon
4	New Objective
7	Quanterix/Neoline
9	Novilytic
2	SCIEX

FOR EXHIBITORS

Move-in: Wednesday, 7:00 pm - 9:00 pm Move-out: Friday, 5:00 pm - 7:00 pm



### WORKSHOPS

### Wednesday April 10

12:00 PM

#### **Registration Open**

Renaissance Shanghai Pudong 4th Floor Lobby

1:00 PM - 3:30 PM

#### **PRE-CONFERENCE WORKSHOPS**

Ballroom I

#### **Special Workshop** (Chinese)

Workshop Leader: Tianyi Zhang, Frontage

▶ 如何获得好的临床试验结果,从临床试验管理的角度 - 温清,济南中心医院 How to Obtain Good Outcome from Clinical Trials, from Clinical Trial Management Perspective

Qing Wen, Jinan Central Hospital

- ▶ 申办方对临床研究中的大分子生物分析项目的管理 -顾为华,齐鲁制药 Sponsor's Management of Large Molecule Bioanalysis Project for Clinical Studies Weihua Gu, Qilu Pharmaceutical
- ▶ 基于FDA新指导原则(2019)的免疫原性生物分析策略 -施鑫,方达医药 Bioanalytical Strategies for Immunogenicity Based on 2019 FDA New Guidance Xin Shi, Frontage

Ballroom II

Emerging Challenges and Issues for Biologics Development and Support: Multiple Modalities for Therapeutic Proteins, Vaccines, Viral Vectors and Oligos

Workshop Leader: Ajai Chaudhary, Merck; Hong Shen, Sanofi; Dobrin Nedelkov, Isoformix; and Emily Ehrenfeld, New Objective

- ► Pharma/Biopharma Perspective and Vision Hong Shen, Sanofi
- ► Clinical Laboratory Workflows, Issues and Needs Dobrin Nedelkov, Isoformix
- ► Integrated Technology and Solutions Emily Ehrenfeld, New Objective

Panel Discussion: Pat Bennett, PPD Labs Hao Jiang, Bristol-Myers Squibb Liling Liu, Genentech Baomin Xin, Shanghai Medicilon



### **PROGRAM**

### Wednesday April 10

5:00 PM - 6:00 PM

**EXECUTIVE ROUNDTABLE** 

Ballroom I

**East Meets West** 

6:00 PM

#### **OPENING RECEPTION & KEYNOTE LECTURE**

Ballroom II

Plan to attend the opening festivities. Greet old friends, meet new friends, and get an overview of the week's events and activities.

Welcome to CPSA Shanghai 2019!

Sponsor's Toast

Given by

Liping Bian, Antpedia

Emily Ehrwenfeld, New Objective

#### **KEYNOTE LECTURE** (CHINESE)

不可逆靶向抗肿瘤药物与血浆蛋白的共价结合

Covalent Binding of Irreversible Targeted Anticancer Drugs to Plasma Proteins

Dafang Zhong, Shanghai Institute of Materia Medica



4th ANNUAL SYMPOSIUM

### Clinical & Pharmaceutical Solutions through Analysis

May 6-9, 2019 • Boston, MA

### Solutions for the Patient: Building Communities One Patient at a Time

Program Co-Chair

Plenary Speaker

Program Co-Chair

Amanda Berg
New Objective

Neil Spooner Spooner Bioanalytical Solutions Alla Kloss Sanofi

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7

Where Technology and Personalized Healthcare Meet!



### Thursday April 11

7:30 AM **Registration Open** 

Renaissance Shanghai Pudong 4th Floor Lobby

8:30 AM - 9:00 AM **OPENING REMARKS** 

Ballrooms I & II Welcome

Mike Lee, Milestone Development Services

Objectives, Format, and Opening Remarks

Min Liu, Merck - Program Chair

9:00 AM - 9:45 AM **PLENARY LECTURE** 

Ballrooms I & II The Invention of MK-8262, a CETP Inhibitor Backup to Anacetrapib

(with Best in Class Properties)

Petr Vachal, Merck

9:00 AM - 5:00 PM **Poster Hall Open** 

Yangtze Ballroom Posters will be available all day today and Friday

9:45 AM **COFFEE BREAK** 

Ballrooms I & II

Sponsored by SCIEX

10:00 AM - 11:30 AM **SYMPOSIUM SESSION** 

The Emerging Area of PKPD Chairs: Kelly Dong, UP Pharma; Jeff Zhang, Novartis

> ► Machine Learning: Taming the Beast of Complex PK/PD Modeling Emile Chen, GlaxoSmithKline

▶ Integrating PK and PD: Incorporation of Biomarker Readouts into PK Designs for Quantitative PK/PD Models

▶ Bridging the Dose-Exposure-Response Relationship, A Case Example

Peiming Ma, GlaxoSmithKLine

11:00 AM - 2:00 PM CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

Edmund Hoppe, Grunenthal

4th Floor Lobby Meet and mingle with vendors offering the latest in technology and services

11:30 AM - 1:30 PM POSTER SESSION / YOUNG SCIENTIST EXCELLENCE AWARD REVIEW

Yangtze Ballroom Session Chairs: Kelly Dong, UP Pharma and Jeff Zhang, Novartis

Review posters and speak with the next generation of up-and-coming scientists as they

present their work and answer questions.





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### 药学研究

药物分析制剂研发临床用药生产GMP&CMC咨询

#### 临床研究

临床I期 BE试验 生物统计 法规事务

#### 生物分析

小分子药物分析 PK生物样本分析 免疫原性分析 生物标记物分析

中美两国 同一质量体系

- 拥有国内首家按照美国FDA标准建立和运营的GLP实验室;
- 顺利通过51次FDA的现场核查,中国生物分析实验室通过NMPA核查70多次;
- 与国内18家机构合作共建临床中心。其中,与吉林大学第一医院合作共建的 I 期临床中心,于2015年10月零缺陷通过美国FDA的现场核查(BE项目)。



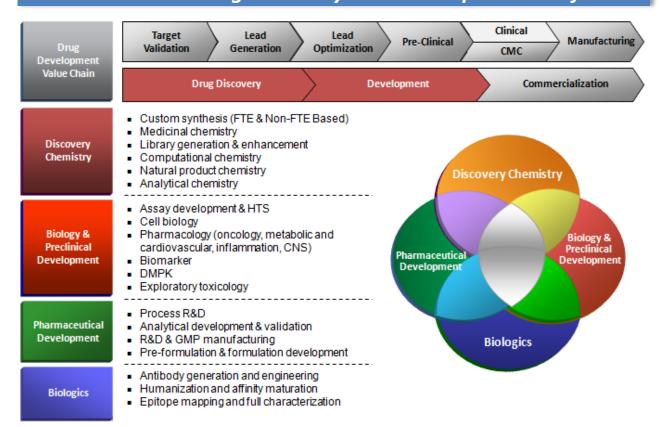
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### **Our Vision**



Strives to become a global, science driven, technology based, quality contract research and manufacturing service provider for the biopharmaceutical industry

### Well Established Drug Discovery and Development Platforms



### INTEGRATED DMPK SERVICE

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Discovery ADME	Study Directors	Discovery BA	In vivo Assays
Metabolite ID	In Life (small animals)	Regulated BA	In vitro Assays
New Methods	In Life (large animals)	Biomarker	48,
Customer FIRST!	Pre-formulation	Peptide	
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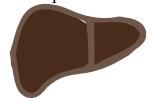






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### Where Technology and Solutions Meet!



#### Mark your calendar!



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March 2020 Columbia, SC USA

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Program Chairs Abhishek Jha

Elucidata **Andrew Lee IMCS** 



April 10-12, 2019 Shanghai, China

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Program Chair

Min Liu



May 6-9, 2019 Boston, MA USA

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Program Chairs Alla Kloss Sanofi

Amanda Berg



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October 28-31, 2019 Philadelphia, PA USA

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**Timothy Olah** Britol-Myers Squibb

**Neil Spooner** Spooner Bioanalytical Solutions



### Thursday April 11

12:00 PM - 1:00 PM LUNCH & LEARN WORKSHOP

Ballroom I Integrated Solutions for NanoFlow and MicroFlow LC-MS:

A Vision for a Validated CPU Sponsored by New Objective

1:30 PM - 3:00 PM PARALLEL SESSIONS TRACKS 1 - 4

1:30 PM - 3:00 PM PARALLEL SESSIONS TRACKS 1 - 4				
Track 2  Advancement of LC-MS Applications in Bioanalysis of Biotherapeutics  Ballroom II				
<ul> <li>Chair: Hao Jiang, Bristol-Myers Squibb</li> <li>▶ Strategies and Challenges for LC-MS/MS Based Peptide Quantification to Support GLP TK and Clinical PK Studies         <i>Yang Xu, Merck</i> <ul> <li>▶ Combining LBA and LC-MS Technologies to Better Support Biologics Development</li></ul></li></ul>				
Track 4 Pharmaceutical Development: Preformulation and Formulation Challenges Rhine Ballroom				
<ul> <li>Chair: Qun Lu, Celgene</li> <li>Formulation Challenges of Poorly Water Soluble Drugs         <ul> <li>Cai Ting, Chinese Pharmaceutical University</li> </ul> </li> <li>Use of Flash Nano-Precipitation (FCP) for Development of Poorly Soluble Compounds         <ul> <li>Sunny Panmai, STA Pharmaceutical</li> </ul> </li> <li>Opportunities and Challenges in Biologics         <ul> <li>Formulation Development</li> <li>Sheng Tu, Wuxi Biologics</li> </ul> </li> </ul>				



### Thursday April 11

3:00 PM	COFFEE BREAK		
	Sponsored by SCIEX PARALLEL SESSIONS TRACKS 5 - 8		
3:30 PM - 5:00 PM			
Track 5 Analytical Technology and Development  Ballroom I  Chairs: Min Li, Huahai Pharmaceutical; Min Liu, Merck  ▶ Advances in UPLC and its Applications in Pharmaceutical Development Naijun Wu, Celgene  ▶ Modern Mass Spectrometry and its Applications in Pharmaceutical Analysis Yuanjiang Pan, Zhejiang University  ▶ ASMS (Affinity-Selection Mass Spectrometry): A New Active Hit Screening Platform Using 2D-HPLC-MS Technique Established at WuXi AppTec Chunhui Ma, Wuxi AppTec		Track 6 Emerging Technology, Methods, and Workflows in Modern Drug Discovery: Generating the Appropriate Data for the Patient  Ballroom II  Chair: Hong Shen, Sanofi  Data Integrity and Risk Management  Yin Xiong, XiHua Scientific Co., Ltd.  Considerations of Analytical Method Development and Validation: Feasibility and Reproducibility  Chuncheng Huang, Wuxi AppTec  MALDI-TOF Mass Spectrometry for Protein Biomarke Analysis  Dobrin Nedelkov, Isoformix	
			Track 7 Focus on Bioequivalence Danube Ballroom
Chairs: Frances Wang, Johnson & Johnson; Tianyi Zhang, Frontage Laboratories  ▶ 口服固体制剂的体内外相关性 - 何仲贵, 沈阳药科大学 In vitro and In vivo Correlation of Oral Solid Dose Formulations Zhonggui He, Shenyang Pharmaceutical University  ▶ 仿制药和原研药的食物影响会不一样吗?处方工艺在食物 影响中的作用初探 - 杨劲, 中国药科大学 Can Food Effect be Different in Generic Drug and Innovative (Reference) Drug? Preliminary Study of Impact of Formulation Technology in Food Effect. Jin Yang, China Pharmaceutical University  ▶ 生物等效性试验(BE)的生物分析要求 - 张天谊 Bioanalytical Requirements in Bioequivalence (BE) Studies Tianyi Zhang, Frontage Laboratories		Chair: Yi Du, Huahai Pharmaceutical  To Be Announced	



### Thursday April 11

6:00 PM DISTINGUISHED SCIENTIST LECTURE & ROUNDTABLE

Ballroom I Sponsored by Antpedia & New Objective

Held in conjunction with CA-CA

**Distinguished Scientist Lecture** 

Ultrasensitive Ambient Mass Spectrometry Immunoassays: Detection of Protein Biomarkers of Some Cancers

Huwei Liu Peking University

Session Chairs: Kelly Dong, UP Pharma

Emily Ehrenfeld, New Objective Dobrin Nedelkov, Isoformix

Session Moderators:

Tianyi Zhang, Frontage Laboratories Baomin Xin, Medicilon Inc. China



22nd ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

October 28 -31, 2019 • Philadelphia, PA USA

### Clinical and Pharmaceutical Analysts United: Human Wellbeing is Our Responsibility

Program Co-Chair

Plenary Speaker

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Timothy Olah Bristol-Myers Squibb

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Where Technology and Solutions Meet!



### Friday April 12

**7:30 AM** Registration Open

Renaissance Shanghai Pudong 4th Floor Lobby

8:30 AM – 9:15 AM PLENARY LECTURE

Ballrooms I & II Application of Multi-Stage Mass Spectrometry (MSn) in Solving Challenging Problems

in Pharmaceutical Industry: From Rapid Structure Elucidation, Drug Degradation

Mechanism Studies, to Detection of Genotoxic impurities

Min Li, Huahai Pharmaceutical Co., Ltd.

9:00 AM – 5:00 PM Poster Hall Open

Yangtze Ballroom Posters will be available all day today

9:15 AM COFFEE BREAK

Sponsored by SCIEX

9:30 AM – 11:00 AM SYMPOSIUM SESSION

Ballrooms I & II Biomarkers: New Area in Bioanalysis

Chairs: Kelly Dong, UP Pharma; Jeff Zhang, Novartis

► Embracing Biomarker Analysis: Beyond the Regular Bioanalysis

Kelly Dong, UP Pharma

▶ Biomarker Validation Activities for non-LBA Technologies. How Do We Bridge the

**Gap to Current Guidance Documents?** 

James Munday, Covance

▶ Ultrasensitive Immunoassay Technologies – Biomarker and PK/PD in Immuno-

Oncology, Autoimmune, Neuroscience, Metabolic and Infectious Diseases

Dan Sikkema, Quanterix

11:00 AM - 2:00 PM CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

4th Floor Lobby Meet and mingle with vendors offering the latest in technology and services

Ballroom I WORKSHOP

**LUNCH & LEARN WORKSHOP** 

The Future of Personalized Healthcare: Integrated Solutions

Sponsored by New Objective

12:00 PM - 1:00 PM



### Friday April 12

#### 1:30 PM - 3:00 PM

#### **PARALLEL SESSIONS** TRACKS 1 - 4

Track 1 Invitro to Invivo Translation and PBPK Modeling  Ballroom I  Chair: Yuan Chen, Genentech  ► Translational Aspects of Drug Discovery	Track 2 New Technologies for in vitro ADME  Ballroom II  Chair: Yu Wang, Pharmaron China  Antisense Oligo DMPK
<ul> <li>Matthew R. Wright, Genentech</li> <li>Utilities of Physiologically-based Pharmacokinetic Modeling in Pediatric Drug Development         Ming Zheng, Bristol-Myers Squibb</li> <li>Towards Prospective Pharmacokinetic Prediction of Organic Anion Transporting Polypeptide (OATP) Substrates         Jialin Mao, Genentech</li> </ul>	Zack Cheng, Zion Pharma  ▶ Quantifying Low Metabolic Clearance in Drug Discovery: In Vitro Assays, Strategies and Human Extrapolation Simon Taylor, Pharmaron
Track 3  New Biotherapeutic Modalities and Bioanalytical Support  Ballroom I	Track 4 Biomarkers from Discovery to Clinic Ballroom I
<ul> <li>Chairs: Pat Bennett, PPD Labs; Hao Jiang, Bristol-Myers Squibb</li> <li>Introduction of New Biotherapeutic Modalities:         Cellular and Gene Therapies         Pat Bennett, PPD Labs</li> <li>Driving Biomarker Research in Chinese Clinical Trials –         Experience Sharing from the Central Lab Perspective         Guo Jingjing, Teddy Lab</li> <li>Utilizing HRMS for Quantitative and Qualitative         Bioanalysis for Drug Development         Min Meng, Denali Medpharma</li> </ul>	<ul> <li>Chair: Liling Liu, Genentech</li> <li>▶ Quantitation of Biomarkers &amp; Racemate Analytes by Chiral Supercritical Fluid Chromatography-Tandem MS         <ul> <li>Liling Liu, Genentech</li> </ul> </li> <li>▶ Bioanalytical Tools Supporting Preclinical and Clinical Applications for Cell and Gene Therapy             <ul></ul></li></ul>

3:00 PM

#### **COFFEE BREAK**

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### Friday April 12

#### 3:30 PM - 5:00 PM

#### **PARALLEL SESSIONS** TRACKS 5 - 6

Track 5 Technologies and Applications for Quantitation in the Clinic	Track 6 Hot Topics in Bioanalysis II
Ballroom I	Ballroom II
Chairs: Emily Ehrenfeld, New Objective; Dobrin Nedelkov, Isoformix  ▶ Emerging Workflows in the Modern Laboratory: Perspectives from Drug Discovery and the Clinic Hong Shen, Sanofi  ▶ Sensitive and Precise Characterization of Combinatorial Histone Modifications by Selective Derivatization Coupled with RPLC-EThcDMS/MS Rijing Liao, Shanghai Institute of Precision Medicine  ▶ Next Generation Clinical Diagnostic Assays Dobrin Nedelkov, Isoformix	<ul> <li>Chair: Tianyi Zhang, Frontage Laboratories</li> <li>Early Human Dose Prediction as a Scoring Metric in Lead Optimization Campaign         Sean Kim, Blueprint Medicines</li> <li>The Scientific Considerations of Developing the Bioanalysis Assay for Low Molecular Weight Heparins Song Zhao, Frontage Laboratories</li> <li>Meaningful Immunogenicity Assessment for Innovative versus Biosimilar Products         Linglong Zou, Henlius</li> </ul>

#### 6:00 PM - 7:30 PM

#### **CPSA SHANGHAI DINNER, AWARDS & CELEBRATION**

Ballroom I & II

Dinner, Awards and Celebration

#### **Closing Toast**

Given by Liping Bian, Antpedia Emily Ehrenfeld, New Objective

#### **Program Chair Recognition**

Mike Lee, Milestone Development Services

### CPSA Shanghai 2020 – Program Chair Announcement

Min Liu, Merck and Mike Lee, Milestone Development Services

### Young Scientist Excellence Award Presentation Kelly Dong, UP Pharma and Jeff Zhang, Novartis





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